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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH, NORTHERN DIVISION

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|---|---|
| ALBION LABORATORIES, INC., a Utah corporation; ALBION INTERNATIONAL, INC., a Nevada corporation; and BRECKENRIDGE PHARMACEUTICAL, INC., a Florida corporation,<br><br>Plaintiffs,<br><br>v.<br><br>TRIGEN LABORATORIES, INC., a New Jersey corporation,<br><br>Defendant. | Case No. 1:09-CV-00126 DAK<br><br>**COMPLAINT**<br><br>**(Jury Trial Demanded)** |

Plaintiffs Albion Laboratories, Inc., Albion International, Inc., and Breckenridge Pharmaceutical, Inc., (collectively, "Plaintiffs") allege and complain of defendant Trigen Laboratories, Inc., as follows:

## THE PARTIES

1. Plaintiff Albion Laboratories, Inc. is a Utah corporation, and plaintiff Albion International, Inc. is a Nevada corporation. Both Albion Laboratories, Inc. and Albion International, Inc. (collectively, "Albion") have their principal place of business at 101 North Main Street, Clearfield, Utah, 84015.

2. Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a Florida corporation with its principal place of business at 1141 South Rogers Circle, Suite 3, Boca Raton, Florida, 33487.

3. Defendant Trigen Laboratories, Inc. ("Trigen") is a New Jersey corporation with its principal place of business at 2400 Main Street, Suite 6, Sayreville, New Jersey, 08872.

## JURISDICTION AND VENUE

4. This Court has original jurisdiction over the subject matter of the First Claim for Relief stated below under 28 U.S.C. §§ 1331 and 1338(a), because it arises under the patent laws of the United States.

5. This Court has original jurisdiction over the subject matter of the Second Claim for Relief stated below under 28 U.S.C. § 1331 and 15 U.S.C. § 1121(a), because it concerns violation of section 43 of the Lanham Act, 15 U.S.C. § 1125.

6. This Court has personal jurisdiction over Trigen because it sells and/or offers to sell the accused products, directly or indirectly, to residents of the State of Utah, and has directly

or indirectly sold multiple units of the accused products in the State of Utah, has directed its activities at Utah residents, and has caused tortious injury in this state.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1400 and 1391 because Trigen is subject to personal jurisdiction in this district.

## GENERAL ALLEGATIONS

### Albion's Leading Position And Reputation As A Supplier Of Mineral Chelates For Human Consumption

8. Since Albion began producing and commercializing mineral chelates for human consumption over 30 years ago, it has invested very significant amounts of money, time, and effort to establish itself as the leading company for the development, scientific understanding, and production of mineral chelates.

9. Albion has invested millions of dollars over the past decades in the scientific study of mineral nutrition generally, and of the benefits of high quality chelated minerals specifically. Albion has financed and conducted hundreds of studies and/or clinical trials, with over 200 of those studies published in peer-reviewed scientific journals.

10. Albion is the preeminent leader in the mineral nutrition industry in working with the United States government and foreign governments to establish definitions of mineral chelates and other mineral organic compounds, to set safety standards and consumption levels, and to create other standards related to mineral chelates.

11. Albion invests heavily in marketing, advertising and branding activities to establish industry and public awareness of its leading role and expertise in the field of mineral nutrition and chelated minerals, and thus to establish and maintain a reputation consistent with its accomplishments in this field.

12. Based on its years of significant investment in the food, pharmaceutical and nutrition industries, producers of human nutritional products associate chelated minerals with Albion. Consumers as well are beginning to recognize and associate Albion with chelated minerals.

13. Albion has also invested millions of dollars into research leading to intellectual property. Albion has prosecuted and secured over 130 patents in multiple countries in the field of mineral nutrition, the chemistry of chelation, production processes, specific applications and methods of using chelated minerals, and the compositional identification and analysis of chelated minerals.

14. Among its intellectual property related to mineral chelates, Albion is the owner by assignment of U.S. Patent No. 6,716,814, entitled "Enhancing Solubility of Iron Amino Acid Chelates and Iron Proteinates" ("the '814 patent"), attached hereto as Exhibit A.

15. Among the mineral chelates manufactured and sold by Albion is ferrous asparto glycinate, an iron amino acid chelate marketed by Albion under the trademark Sumalate®.

**Breckenridge's Well-Established Role As A Supplier Of Generic Prescription Products, Including Products Containing Iron Chelates**

16. For over 25 years, Breckenridge has been in the business of developing and marketing pharmaceutical products, which it sells to retailers, wholesalers, distributors, and other purchasers of such products nationwide.

17. As is well known, pharmaceutical products are often available as a brand product and also as one or more "generic" versions that contain the same active ingredients, dosage form, and strength as the brand product.[1]

18. The market for any particular generic product typically begins with one established brand-name product, which is joined later by lower-cost, generic alternatives. Breckenridge competes in the pharmaceutical market by developing and selling such generic alternatives.

19. Before introducing any new generic pharmaceutical product into the marketplace, Breckenridge invests significant resources to ensure that the formulation, testing, and manufacture of each such product comply both with internal quality-control release standards and with all applicable U.S. Food and Drug Administration regulations, including current Good Manufacturing Practices, and that the active ingredients are properly listed and disclosed in all labeling.

20. Breckenridge also ensures that for each product, stability testing has been performed and that the results thereof are sufficient to support the expiration assigned to that product. The assignment of an expiration date to a prescription pharmaceutical product is understood in the pharmaceutical industry as a representation that appropriate stability testing has been performed, and that the results of such testing support that expiration date.

21. Because of the time and effort Breckenridge has expended in assuring the quality of its products, it has established a high reputation in this generic market.

[1] The term "generic" is not used herein in the narrower sense sometimes applied only to drugs listed in an official compendium as therapeutically equivalent, but in the widely-used meaning of "multisource" products with the same active ingredients, dosage form, and strength as the comparable brand product.

22. Among the generic prescription pharmaceutical products marketed by Breckenridge are certain products containing iron for use in treating anemia ("Hematinic Products").

23. Breckenridge is the exclusive licensee of the Albion '814 patent for a particular field of use, including generic prescription Hematinic Products in the United States that contain ferrous asparto glycinate, an iron chelate, mixed with organic acids pursuant to the method claimed by the '814 patent.

24. Among the prescription hematinic products marketed by Breckenridge under this exclusive license are: Multigen, Multigen Folic, Multigen Plus, Ferrex 150 Forte Plus, and Vinate PN Care (collectively, the "Breckenridge Hematinic Products"). The product inserts for the Breckenridge Hematinic Products are attached hereto as Exhibit B.

25. These Multisource Breckenridge Hematinic Products contain the identical active ingredients, in the same dosage form and strength, as the brand products formerly marketed under the brand names of (respectively) Chromagen, Chromagen FA, Chromagen Forte, Niferex 150 Forte, and PreCare Premier (the "Brand Hematinic Products"). The product insert for several of the Brand Hematinic Products is attached hereto as part of Exhibit C.

26. Wholesalers, distributors, retailers (such as pharmacies), and other purchasers of generic pharmaceutical products often choose among several competing versions of a generic product to dispense at the retail level, and in so doing rely on the representations of the marketer, and the listings and "links" provided by industry databases. These databases "link" a particular generic alternative with a particular brand product, based on information supplied to them by the

generic pharmaceutical company indicating that the generic alternative product contains the same active ingredients, in the same dosage form and strength, as the brand product.

27. Consistent with normal industry practice, prescriptions continue to be written for the Brand Hematinic Products, which are filled by the dispensing of generic alternatives that have been linked to the Brand Hematinic Products, including Breckenridge's Hematinic Products.

**The Recent Introduction By Trigen Of Its Defective Competing Products**

28. Trigen also markets Multisource prescription pharmaceutical products, and in 2009, began marketing products under the names of Trimagen, Trimagen FA, Trimagen Forte, Triferex 150 Forte, and Advance Care Plus Prenatal (the "Trigen Hematinic Products"). The packaging and product inserts for several of the Trigen Hematinic Products are attached hereto as Exhibit D.

29. Trigen markets, promotes, advertises, offers for sale, sells, and distributes the Trigen Hematinic Products to customers, including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, and/or others, throughout the United States, including in the State of Utah.

30. Trigen promotes and markets the Trigen Hematinic Products as generic alternatives to, respectively, the Brand Hematinic Products of Chromagen, Chromagen FA, Chromagen Forte, Niferex 150 Forte, and PreCare Premier.

31. The labeling for the Trigen Hematinic Products, including the product inserts, indicates that they contain the identical active ingredients, in the same dosage form and strength,

as the respective Brand Hematinic Products, including the elemental iron which is necessary to treat anemia.

32. By representing and advertising that the Trigen Hematinic Products contain the stated amounts of active ingredients, Trigen also represents and advertises that it follows certain industry standards, and that those amounts of those active ingredients, within such ranges as provided by the applicable compendial standards, will be available by ingestion by a human consumer.

33. The packaging for the Trigen Hematinic Products also contains expiration dates, representing that appropriate stability testing has been performed, and that the results of such testing support those expiration dates.

34. Trigen has provided these product inserts and the information thereon to the pharmaceutical industry database companies, and thus has induced the databases to "link" the Trigen Hematinic Products to the Brand Hematinic Products -- the same products to which the Breckenridge Hematinic Products have also been linked.

35. Additionally, Trigen explicitly or implicitly represents, directly or indirectly, that the Trigen Hematinic Products are generic equivalents of, and/or substitutable for, and may be dispensed to fill prescriptions for, the respective Brand Hematinic Products.

36. Thus, Trigen also explicitly or implicitly claims that the Trigen Hematinic Products contain an iron amino acid chelate in the form of ferrous asparto glycinate, mixed with the same solubilizing organic acids present in the Brand Hematinic Products.

37. Upon information and belief, Trigen has not scientifically determined whether or not the Trigen Hematinic Products are the generic equivalents of, and/or substitutable for, the Brand Hematinic Products.

38. By virtue of at least the foregoing representations, Trigen has made sales of the Trigen Hematinic Products to parties that would otherwise have purchased the Breckenridge Hematinic Products in place of the Brand Hematinic Products, and has forced Breckenridge to lower its prices in order to avoid losing additional sales to Trigen.

39. Upon information and belief, the foregoing representations are literally false and/or misleading.

40. By representing that its sub-potent Hematinic Products contain ferrous asparto glycinate, an iron chelate, Trigen is causing irreparable harm to the reputation of Albion, which has invested so much time and effort to establish the benefits of mineral chelates and is now associated with mineral chelates by the industry and the public, and to the reputation of Breckenridge, which has worked for years to establish generic prescription products as acceptable and equivalent alternatives to brand prescription products.

**FIRST CLAIM FOR RELIEF**
**(Patent Infringement)**

41. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

42. Trigen manufactures, uses, sells, and offers to sell the Trigen Hematinic Products, and thereby directly infringes, contributorily infringes, and/or induces infringement of, the '814 patent.

43. Plaintiffs have been injured thereby, in an amount to be determined at trial.

44. Upon information and belief, the infringement of the '814 patent by Trigen is willful.

45. Upon information and belief, Trigen will continue its infringement of the '814 patent unless its acts of infringement are restrained and enjoined by this Court. Due to Trigen's continuing acts of infringement of the '814 patent, Plaintiffs have suffered and/or will suffer irreparable injury for which they have no adequate remedy at law.

**SECOND CLAIM FOR RELIEF**
**(Violation Of The Lanham Act)**

46. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

47. Trigen has engaged in false advertising, actionable under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), by using in commerce and in connection with its Hematinic Products, false and misleading descriptions and representations of fact, and other words, terms, and devices that misrepresent the nature, characteristics, and/or qualities of its Hematinic Products, including by way of illustration but not limitation, explicit and/or implicit representations that the Trigen Hematinic Products contain certain amounts of elemental iron and other active ingredients, and that such ingredients will become available to a human consumer upon ingestion; and explicit and/or implicit representations that the Trigen Hematinic Products are generic equivalents of, substitutable for, and may be dispensed to fill prescriptions for, the respective Brand Hematinic Products.

48. Plaintiffs have been injured thereby, in an amount to be determined at trial.

49. Upon information and belief, Trigen will continue its violation of the Lanham Act unless this violation is restrained and enjoined by this Court. Due to Trigen's continuing acts of

false advertising, Plaintiffs have suffered and/or will suffer irreparable injury for which they have no adequate remedy at law.

## PRAYER FOR RELIEF

**WHEREFORE,** Plaintiffs request that the Court:

(a) Preliminarily and permanently enjoin Trigen, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from making, using, offering to sell, or selling the Trigen Hematinic Products;

(b) Enter judgment against Trigen for compensatory damages by reason of its infringement of the '814 patent, as determined at trial, but not less than a reasonable royalty;

(c) Determine that such infringement was willful, and award treble damages to Plaintiffs by reason thereof;

(d) Declare this case to be "exceptional" within the meaning of 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys' fees, expenses and costs of this action;

(e) Preliminarily and permanently enjoin Trigen, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from falsely representing the nature and characteristics of the Trigen Hematinic Products, and from falsely representing that the Trigen Hematinic Products are generic equivalents of, or substitutable for, the respective Brand Hematinic Products;

(f) Enter judgment against Trigen for compensatory damages by reason of its violation of the Lanham Act, as determined at trial; and

(g) Enter an Order granting Plaintiffs such other and additional relief against Trigen as may be just and proper under the circumstances.

**DEMAND FOR TRIAL BY JURY**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand a trial by jury of all issues properly triable to a jury in this case.

DATED this 25th day of September, 2009

L. Rex Sears
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BRECKENRIDGE PHARMACEUTICAL, INC.

By /s/ Janna. J. Lewis

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